510(k) Summary

Name of 510(k) Sponsor	Playtex Products, LLC 6 Research Drive Shelton, CT 06484
Contact Information	Pushpa Rao, Ph.D., D.A.B.T., R.A.C. Senior Manager, Product Safety/North America Regulatory Affairs Research & Development Playtex Products, LLC 75 Commerce Drive Allendale, NJ 07401 Telephone: 201-785-8070 Facsimile: 201-785-8202
Summary prepared on	September 5, 2013
Pre-Market Notification #	
Reason for Submission	Changes were made to the applicator color compared to the predicate device. These changes do not affect the intended use or alter the fundamental scientific technology of the device. In addition, the efficacy of the device has not been affected as there were no changes made to the tampon pledget and absorbency ranges. A risk assessment is provided in this Special 510(k) pre-market notification and confirms that these changes do not raise any safety concerns for the proposed device.
Name of Device Trade Name	Playtex® (Scented) Sport Fresh Balance™ Tampons Playtex® (Unscented) Sport Fresh Balance™ Tampons
Common Name	Menstrual Tampon, Scented and Unscented
Classification Name	Scented or scented deodorized menstrual tampon and Unscented menstrual tampon
Classification Code	HIL, HEB
Predicate Devices	Playtex® Sport (Scented) Tampons with Odorshield ™ and Playtex® Sport (Unscented) Tampons with Odorshield™ (K111684)
Device Description	Scented (or scented deodorized) and unscented menstrual tampons for the absorption of menstrual fluid. The tampon consists of a pledget, string and applicator (barrel and plunger).
Intended Use	Playtex scented and unscented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.
Technological Characteristics	The modified tampons have the same technological characteristics as the predicate devices (K111684) as they have the same design, absorbency and

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	mode of action. The fiber and materials in contact with the vaginal wall are also the same. The only difference in the modified tampons from the predicate tampons is the composition of the colorants incorporated into the polyethylene resin used to manufacture the applicator.
Biocompatibility Tests	Deemed not applicable for the modified device based on the results of the Leaching Studies. Biocompatibility testing was performed on the predicate device to confirm the tampon material safety.
Performance Testing	No changes were made to the tampon pledget. Syngyna testing was performed and the results confirmed that the absorbance ranges are the same as the predicate device and comply with 21 CFR §801.430(f)(2).
Conclusion	As confirmed by our risk assessment and leaching studies, the proposed modification on the applicator colorant has no impact on the safety or efficacy of the device. The proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2013

Playtex Manufacturing, Inc.
Playtex Products, LLC
% Pushpa Rao, Ph.D., D.A.B.T, R.A.C
Senior Manager, Product Safety/North America
Regulatory Affairs
75 Commerce Drive
Allendale, NJ 07401

Re: K132819
Trade/Device Name: Playtex® (Scented) Sport Fresh Balance™ Tampons
Playtex® (Unscented) Sport Fresh Balance™ Tampons
Regulation Number: 21 CFR§ 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL, HEB
Dated: September 5, 2013
Received: September 9, 2013

Dear Pushpa Rao,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: K132819

Playtex® (Scented) Sport Fresh Balance™ Tampons
Playtex® (Unscented) Sport Fresh Balance™ Tampons

Indications For Use:

Playtex scented (or scented deodorized) and unscented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.

Absorbency Ranges:	Absorbs menstrual flow < 6 grams (Light)
	Absorbs menstrual flow 6-9 grams (Regular)
	Absorbs menstrual flow 9-12 grams (Super)
	Absorbs menstrual flow 12-15 grams (Super Plus)

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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